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10/628,464	07/29/2003	Jon Elliot Adler		4703

  

EXAMINER	
HOWARD, ZACHARY C	

  

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/628,464	ADLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 118-141 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 118-141 is/are rejected.
- 7) ☐ Claim(s) 118, 120 and 124 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 4/27/07 has been entered in full. Claims 93-117 are canceled. New claims 118-141 are added.

Claims 118-141 are under consideration in the instant application.

### ***Withdrawn Objections and/or Rejections***

The following page numbers refer to the previous Office Action (2/15/07).

All objections and/or rejections of claims 93-117 are moot in view of Applicants' cancellation of these claims.

It is noted that claims 93-117 were rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph at pg 4-5 as being indefinite (the metes and bounds of the recited phrase "contained in" were unclear). New independent claim 118 (and dependent claims 120-123 and 128-141) does not contain this phrase, and therefore this rejection has not been applied to these new claims. However, new dependent claim 119 and independent claim 124 each use the phrase "contained in" in reference to a nucleic acid sequence, and the metes and bounds of the phrase remain unclear. Therefore, this rejection has been set forth below for claims 119 and 124-127 (claims 125-127 depend from claim 124).

It is noted that claims 106-108 were rejected under 35 U.S.C. § 101 at pg 5 as encompassing non-statutory subject matter (naturally occurring non-isolated host cells within an organism that contained the recited nucleic acid sequences). New claims 130-132 and 134-141 are limited to isolated or recombinant host cells. Therefore, this rejection has not been applied to these new claims.

It is noted that claims 93 and dependent claims 94-117 were rejected under 35 USC § 112, 1<sup>st</sup> paragraph at pg 6 for containing new matter (hybridization conditions including 0.02X SSC, which was not specifically taught in the specification). New independent claims 118 and 124 recite hybridization conditions that include 0.1 X SSC, which is taught by the specification on page 15, paragraph [0044]. Therefore, this rejection has not been applied to any of the new claims.

It is noted claims 93 and 96-98 were rejected under 35 U.S.C. 102(b) at pg 7-8 as being anticipated by NCBI Entrez Nucleotide, database record for Locus AC092214, Version AC092214.1, 29 June 2001. This rejection was based on these claims encompassing fragments of polynucleotides of SEQ ID NO: 1 and fragments of polynucleotides encoding SEQ ID NO: 2. The new claims do not encompass such variants and therefore this rejection has not been applied to any of the new claims.

### ***Claim Objections***

Claims 118, 120 and 124 are objected to because of the following informalities:

(1) In claim 118, the second line of part (iii) recites "nucleic acid sequence of in SEQ ID NO: 1..." For clarity, this should be amended to recite, "nucleic acid sequence of SEQ ID NO: 1..."

(2) In claim 120, line three recites, "...at least one bitter specifically bound..." This recitation appears to be missing the word "ligand". For clarity, this should be amended to recite, "...at least one bitter ligand specifically bound..."

(3) In claim 124, the second line of part (i), the word "contained" is misspelled as "contasined".

(4) In claim 124, the fourth line of part (ii) the word "specifically" is misspelled as "spcifically".

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 130-132 and 134-141 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated cell containing the isolated cell containing the isolated nucleic acid sequence of claim 118, does not reasonably provide enablement for a non-isolated recombinant cell comprising said

nucleic acid sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the Office Action of 3/30/05, the pending claims were rejected for encompassing host cells within an organism, such as would be used in gene therapy (pg 11) In response, the claims were limited to "isolated" host cells, and the rejection was withdrawn in the Office Action of 2/22/06. However, new claims 130-132 and 134-141 are each directed to an "isolated or recombinant host cell". The recitation of "recombinant host cell" encompasses non-isolated host cells found within an organism. Therefore, the rejection set forth at pg 11 of the 3/30/05 Office Action is herewith applied to the new claims.

The specification on page 33-35 teaches systems of expression of T2R76 and Examples 2 and 3 on pages 70-71 discuss expression of T2R76. All of the teachings in the specification are directed to isolated host cells; there are no examples directed towards systems of expression within an organism. It is acknowledged that the level of skill of those in the art is high, but it is not disclosed and not predictable from the limited teachings of the prior art and specification if the expression system of the present invention could be used for gene therapy. Thus the specification fails to teach the skilled artisan how to use host cells comprising the T2R76 polynucleotides for expression within an organism without resorting to undue experimentation. The specification has not provided the person of ordinary skill in the art the guidance necessary to be able to use the host cells comprising the polynucleotide for the above stated purpose. Due to the large quantity of experimentation necessary to determine if the host cells comprising the T2R76 polynucleotide could be used for gene therapy, the lack of direction/guidance presented in the specification regarding same, lack of working examples and the limited teachings of the prior art and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use the claimed invention. What Applicant has provided is a mere wish or plan and an invitation to experiment to determine if the host cells comprising the T2R76 polynucleotide could be used within an organism for gene therapy.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 118-141 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 118 recites, "said isolated nucleic acid sequence is operably linked to a heterologous nucleic acid sequence that provides for the expression thereof in a recombinant host cell containing said isolated nucleic acid sequence". The metes and bounds of the phrase "operably linked" are indefinite because the phrase is not taught in the specification. The specification teaches that "[t]he term "operatively linked", as used herein, refers to a functional combination between a promoter region and a nucleotide sequence such that the transcription of the nucleotide sequence is controlled and regulated by the promoter region" (pg 21). However, it is unclear whether "operably linked" has the same definition as "operatively linked" or not. Therefore, for purposes of prosecution, the term "operably linked" has been interpreted broadly to encompass any linked heterologous nucleic acids; for example, an entire gene (with its own homologous promoter) comprised within a heterologous plasmid. For example, "operably linked" has been broadly interpreted to encompass a bacterial artificial chromosome comprising a heterologous mammalian sequence comprising a gene with its native promoter.

Claim 119 is indefinite because it recites "one bitter ligand specifically bound by the T2R76 polypeptide contained in SEQ ID NO: 2" in line 4. The metes and bounds of the phrase "contained in" are unclear. It is unclear if "polypeptide contained in SEQ ID NO: 2" is limited to a polypeptide consisting of SEQ ID NO: 2, or whether it encompasses short polypeptides (fragments) that are "contained in" the longer sequence of SEQ ID NO: 2.

Claim 124 recites (in part (i), lines 2-4), "...the T2R76 polypeptide contained in SEQ ID NO: and which polypeptide specifically binds to a bitter ligand that is specifically bound by the T2R76 polypeptide of SEQ ID NO:;". This is indefinite for two reasons:

(1) Neither of the two references to a "SEQ ID NO:" includes the number of the sequence. For purposes of prosecution, the claim will be interpreted broadly to encompass SEQ ID NO: 2, because this is the only T2R76 polypeptide sequence identified in the instant specification.

(2) As with claim 119, the recitation of "contained in" (here misspelled as "contasined in" renders the metes and bounds of the claim indefinite.

The remaining claims are rejected for depending from an indefinite claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 118-124 are rejected under 35 U.S.C. 102(a) as being anticipated by NCBI Entrez Nucleotide, database record for Locus AC092214, Version AC092214.2, 15 September 2001, 60 pages. The earliest date to which the instant application claims priority is July 29<sup>th</sup>, 2002. This rejection was set forth previously at page 6-7 of the 2/15/07 Office Action for claims 93-98 (now cancelled); this rejection is herewith applied to new claims 118-124.

Applicants' arguments (4/27/07; pg 7) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response Applicants argue that "the claims are amended to overcome the prior art rejection. In particular the claims now provide for the isolated hT2R76 sequence to be operably linked to a heterologous promoter or for the isolated hTR76 sequence to be comprised in a vector that provides for the expression thereof in an or isolated or recombinant host cell" (pg 7).

Applicants' arguments have been fully considered but are not found persuasive. Applicants state that the new claims are limited to an isolated hT2R76 sequence that is linked to a heterologous promoter. However, new claim 118 actually recites that the isolated hT2R76 sequence is operably linked a heterologous sequence rather than to a heterologous promoter. Furthermore, the phrase "operably linked" is not defined in the specification (see the section titled "Claim Rejections - 35 U.S.C. 112, 2nd Paragraph") and has been interpreted to encompass as any type of nucleic acid linkage. As such, claim 118 encompasses a human TR276 gene with its own promoter linked to a heterologous sequence. The RP11-811J9 clone describe in the record for AC092214.2 is a bacterially artificial chromosome (BAC) comprising a human chromosomal sequence that encodes a protein that is 100% identical to SEQ ID NO: 2. Furthermore, a BAC containing one or more mammalian genes (each comprising their native promoters) is inherently capable of expression in mammalian cells. For example, Baker et al (1997. Nucleic Acids Research. 25(10): 1950-1956; cited here solely to support inherency) teaches a "method of introducing BACs into eukaryotic cells using BAC DNA" (pg 1956) and expression of a human gene located in a BAC. As set forth in the 2/15/07 Office Action, AC092214.2 between residues 157151-158107 contains a nucleic acid sequence that encodes a protein with 100% identity to SEQ ID NO: 2. However, the record for AC092214.2 contains over 155,000 residues upstream of this sequence which contain the promoter for expression of the human T2R76 gene.

Therefore, the record for AC092214.2 anticipates new claims 118.

Claims 119-123 each depend from claim 118 and encompass the same nucleic acids described above; therefore, AC092214.2 also anticipates new claims 119-124.

Similarly, new claim 124 is directed to an expression vector containing an isolated sequences encoding SEQ ID NO: 2, wherein said vector is capable of providing for the expression of said T2R polypeptide in a recombinant host cell containing said expression vector. As such, this claim also encompasses the BAC comprising human T2R76 taught by the record for AC092214.2. Therefore, AC092214.2 also anticipates new claim 124.



**Conclusion**

No claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646